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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/713,498	11/15/2000	Chaoying Zhao	014938.0003	4672

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CHRISTOPHER J. ROURK  
AKIN, GUMP, STRAUSS, HAUER & FELD, L.L.P.  
P O BOX 688  
DALLAS, TX 75313-0688

EXAMINER

PAK, JOHN D

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 11/04/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/713,498

Applicant(s)

ZHAO, CHAOYING

Examiner

JOHN D PAK

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 19 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 20-25, 27, 28 and 30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20-25, 27, 28 and 30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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Claims 20-25, 27-28 and 30 are pending in this application.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 20-25, 27-28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/08500 for the reasons fully stated in Paper No. 9 (3/26/02) with respect to the then-pending claims 1-7.

WO 98/08500 discloses a hypertonic composition comprising L-arginine, sodium chloride (including 6 wt%, see claim 14) and hetastarch (hydroxyethyl starch, minimum 5 wt%, see Table 3). See claims 1-3, 6-7, 10-11, 13-14). Hypertonicity lowering to 7.5 wt% is suggested (p. 7, line 22 to p. 8, line 2). Additional ingredients to make the hypertonic solution are disclosed (p. 10, lines 20-26). Inorganic bases are disclosed (paragraph bridging pages 10 and 11).

Although the cited reference contains L-arginine and the claims are written in "consisting essentially of" language without specific recitation of L-arginine, it is the Examiner's position that the consisting essentially of language does not preclude the instant claims from containing L-arginine. Inclusion of L-arginine would not materially affect the novel and basic characteristics of applicant's invention. With the L-arginine, the composition would still be useable in the same manner in the same pharmaceutical applications.

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Although specific MW of hydroxyethyl starch and specific mixing steps are not expressly disclosed, the ordinary skilled artisan would have been motivated to utilize well known, physiologically acceptable hydroxyethyl starch, which have the physical characteristics that are recited in the claims, and the ordinary skilled artisan would also have been motivated to mix the ingredients to formulate an injectable, physiologically acceptable solution. Claimed NaCl and hydroxyethyl starch concentrations clearly overlap with those of the cited reference, and the reference also suggests an advantage of lower than 7.5% saline.

Although sodium bicarbonate and other substances recited as "third substance" are not expressly disclosed, it must be noted that since 0 w/v% is encompassed, only dependent claim 28 requires its presence. Furthermore, the cited reference suggests addition of other ingredients to make up the injectable hypertonic solution, and sodium bicarbonate is a well known and well tolerated substance in such pharmaceutical applications.

For these reasons, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOHN D PAK whose telephone number is (703)308-4538. The examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703)308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-1235.



JOHN PAK  
PRIMARY EXAMINER  
GROUP 1000